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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,687	07/15/2003	Tetsuro Ogawa	P23556	5517
7055	7590	03/29/2006	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C.			GROUP, KARL E	
1950 ROLAND CLARKE PLACE			ART UNIT	
RESTON, VA 20191			PAPER NUMBER	
			1755	
DATE MAILED: 03/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,687

Applicant(s)

OGAWA ET AL.

Examiner

Karl E. Group

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 7, 9-15, 17-22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 9-15, 17-22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-13-06</u> | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-13-06 has been entered.

Information Disclosure Statement

1. Patent 4960773 is listed on the PTO-1449 has not been considered since it is not clear how xanthine derivatives relate to the claimed glass composition. Patents 5356436 and 5232878 have been previously cited.
2. Applicants are requested to submit the Japanese document listed as 4-36107. It is clear from the drawings that the document supplied does not correspond to the translation. The translation has been considered. The translation of 2001-130927 has not been received therefor the foreign document has not been considered.
3. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3,5,9-12,15,20,21,22,24,25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims stand rejected as indefinite for the terminology "sintered calcium phosphate glass". This is considered misleading because a sintered glass is NOT formed. The glass is added as a sintering aid in amounts of .5-10% to a calcium phosphate ceramic (NOT GLASS). Note the materials set forth in claim 11 are not glass materials. The glass is not being sintered, the calcium phosphate ceramic, which is not glass, is being sintered. The claims as currently written read on a sintering aid (a material that aids in the promotion of sintering materials) that is sintered. A sintered sintering aid.

Claim 11 is considered outside the scope of claim 1 because it requires phosphate containing compounds while claim 1 excludes phosphate from the glass.

Claims 10 and 20 fail to further limit the claim from which it depends. The independent claims set forth sintering aid.

Claim Rejections - 35 USC § 102 and 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1,5,10,12,14,15,18,20-22,24,25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pfeil et al (4,135,935), for reasons of record.

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Applicants' argument that Pfeil et al fail to teach a glass transition temperature 790°C or lower is not persuasive in overcoming the rejection because applicants have not shown by way of tangible evidence that the glass of Pfeil et al is higher than 790°C.

Secondly the limitation "substantially free of P_2O_5 " does not exclude P_2O_5 because "substantially" is considered to be less than 50% and applicants' disclosure fails to define "substantially free" as meaning a specific maximum amount.

As to the limitation "is a sintering aid", the limitation is considered to be an intended use. The claims still claim a "glass".

The intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

It should also be noted that sintering takes place therefor the glass may be considered a sintering aid. The rejection of claim 12 is also considered proper for the above reasons.

Applicants argue Pfeil et al fail to teach the inclusion of B_2O_3 of claim 14. Claim 14 fails to set forth any minimum amount therefor the it is considered an optional component.

As to the bioactivity of the glass mixture in Pfeil et al, the glass is used as an implant material and therefor must have bioactivity. Furthermore, the claims are silent as to any quantitative values for bioactivity, strength or sinterability.

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As to the wollastonite, the claims are drawn to a glass, which may be crystallized, not a crystallized glass.

8. Claims 1-3,5,7,9-11,22,24,25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fuji et al (4,708,652), for reasons of record.

Applicants' argument that Fuji et al fail to teach a glass transition temperature 790°C or lower is not persuasive in overcoming the rejection because applicants have not shown by way of tangible evidence that the glass of Fuji et al is higher than 790°C.

Secondly the limitation "substantially free of P₂O₅" does not exclude P₂O₅ because "substantially" is considered to be less than 50% and applicants' disclosure fails to define "substantially free" as meaning a specific maximum amount. Furthermore, P₂O₅ is an optional component.

As to the limitation "is a sintering aid", the limitation is considered to be an intended use. The claims still claim a "glass".

As to bioactivity because the material is for a biological implant, in order for the material to be successful it must have some bioactivity. Furthermore, Fuji et al teach "excellent in not only biological affinity but also mechanical strength", column 2, lines 1-2, see In re Malagari, 182 U.S.P.Q. 549. A reference may be used for all it realistically teaches and not the specific disclosure of the examples, In re VanMater 144 USPQ 421 (1965).

As to claim 7, the limitation "at least one of" is considered a Markush group therefor only one of the conditions must be met. Fuji et al teach 0-15 mole% B_2O_3 and 10-30 Na_2O .

9. Claims 1,2,5,7,9,10,17,19,22,24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suh et al (5,634,956), for reasons of record.

Applicants' argument that Suh et al fail to teach a glass transition temperature $790^{\circ}C$ or lower is not persuasive in overcoming the rejection because applicants have not shown by way of tangible evidence that the glass of Suh et al is higher than $790^{\circ}C$.

As to claim 17, the limitation is a Markush limitation and only one of the conditions must be met. Suh et al clearly teach .1-1% CaF_2 .

10. Claims 1-3,5,7,9,10,12-15,17-20,22,24 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Japanese document 61-205637, for reasons of record.

Applicants' argument that the Japanese document fails to teach a glass transition temperature $790^{\circ}C$ or lower is not persuasive in overcoming the rejection because applicants have not shown by way of tangible evidence that the glass of Fuji et al is higher than $790^{\circ}C$.

As to excluding the Japanese document does not teach the presence of this component.

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The sintering aid limitation is considered an intended use, a glass is being claimed. The rejected claims are NOT claiming a sintered calcium phosphate but a glass.

As to claim 7, the examples in JP '637 teach the presence of B_2O_3 , P_2O_5 and Na_2O within the ranges of the claims.

As to claim 12, sintering aid is considered an intended use and examples 6 and 7 teach the presence of Na_2O .

As to claim 13, the Japanese document teaches the presence of both Na_2O and CaF_2 .

As to claim 14, example 6 includes Na_2O and excludes B_2O_3 .

As to claim 17 the claim does not require both Na_2O and CaF_2 therefor the argument is not persuasive in overcoming the rejection.

11. Claims 12,14,15,17-20,25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kume et al (4,443,550), for reasons of record.

As to claims 12 and 14, 0-4 wt% Na_2O falls within the claimed range of .1-5 mole%. The examples of Kume et al include Na_2O .

As to claim 17 the claim does not require both Na_2O and CaF_2 therefor the argument is not persuasive in overcoming the rejection.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-3,5,7,9-15,17-22,24 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/962557. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons set forth.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Patent and Trademark procedure is not withdrawing the rejection because 10/962557 is not a patent so the present application may be sent to issue. A terminal disclaimer is still required before the application may be sent to issue, even if the rejection is based upon and application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl E. Group whose telephone number is 571-272-1368. The examiner can normally be reached on M-F (6:30-4:00) First Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Karl E Group
Primary Examiner
Art Unit 1755

Keg
3-20-06